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FROM	Daniel J. Hulseberg	VOICE NO.	1 212 408-2524
DATE	September 15, 2008	FAX NO.	1 212 259-2524
PAGES	8	RETURN TO	J. Chumney
TO	Commissioner for Patents United States Patent and Trademark Office	FAX NO.	571 273 ~~8100~~ 7755
		VOICE NO.	0100

MESSAGE

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ATTORNEY/EMPLOYEE NO. [redacted] 06012

CRITICAL DEADLINE, SEND BY

Attorney Docket No. 077843.0113

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: : U.S. Patent No. 5,451,233 (U.S.S.N. 08/208,972)

Issued: : September 19, 1995 Regulatory Approval Product: XIENCE™ V EECSS

Inventors : Paul G. Yock

For : Angioplasty Apparatus Facilitating Rapid Exchanges

INTERVIEW SUMMARY

SUBMITTED VIA FAX (571) 273-0100
Mail Stop: Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant acknowledges with appreciation the courtesy extended by Ms. Till during the interview with the undersigned at the U.S. Patent and Trademark Office ("USPTO") on September 3, 2008. In accordance with 37 C.F.R. § 1.2, Applicant summarizes herewith the details of the interview.

The interview was initiated pursuant to the duty of disclosure under 37 C.F.R. § 1.765 to identify the type and scope of information that may be considered material by the USPTO to a determination of entitlement to the extension sought pursuant to 35 U.S.C. § 156 for U.S. Patent No. 5,451,233 ("the '233 Patent"). During the interview, the following topics were discussed:

1. General background of the development, use and regulatory approval of rapid exchange catheters, bare-metal stent systems, and drug eluting stent systems, respectively. In support of this discussion, samples of the MULTI-LINK VISION® Coronary Stent System and the XIENCE™ V Everolimus Eluting

Coronary Stent System, respectively, were shown.

2. Summary of all prior litigation involving the '233 Patent, including *Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc.* (C.A. No. 95-03577).

3. Medtronic, Inc.'s Notice of Motion and Motion to Modify Injunction after October 29, 2008; Memorandum of Points and Authorities in Support Thereof ("Motion") dated August 15, 2008, as filed in the United States District Court in the Northern District of California.

4. The Citizen's Petition dated August 19, 2008, as filed on behalf of AngioScore, Inc. with the Food and Drug Administration.

5. The USPTO's position regarding the applicable statutes, rules and case law for a patent term extension under 35 U.S.C. § 156 based upon regulatory review of a medical device, as set forth in the letter from the USPTO to the Honorable Howard L. Berman dated February 8, 2008; a copy of which is enclosed for reference.

Although not necessarily material or adverse to any determination of entitlement to the extension sought, Applicant will provide a written summary of topics 1 and 2, as well as a copy of the Motion and corresponding reply by Applicant for topic 3 and the Citizen's Petition and corresponding reply by Applicant for topic 4. These materials will be submitted to the USPTO as soon as practical after the corresponding reply is filed by Applicant.

Date: September 12, 2008

Respectfully submitted,

Daniel J. Hulseberg
Patent Office Reg. No. 36,554

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE

The Honorable Howard L. Berman
Chairman, Subcommittee on Courts,
the Internet, and Intellectual Property
Committee on the Judiciary
House of Representatives
Washington, D.C. 20515-6216

FEB 8 2008

Dear Mr. Chairman:

Thank you for your letter to Under Secretary and Director Jon W. Dudas inquiring about how the United States Patent and Trademark Office (USPTO) interprets the patent term extension provisions of the patent laws for medical devices. We appreciate hearing from you.

Your general understanding of the 1984 Hatch-Waxman Act is correct; however, there are many nuances of application of patent term restoration to medical devices subject to regulatory review by the Food and Drug Administration (FDA).

At the third paragraph on page one of your letter, you ask the question "which patent in a multi-patented component device may be extended." Section 156 of Title 35 of the United States Code sets forth several requirements that must be met before the USPTO can extend the term of a patent. *See*, 35 U.S.C. §§ 156 (a)(1)-(a)(5), (d)(1), & (o)(1). Relevant requirements include:

(i) the patent must claim the approved product;

(ii) the term of the patent must not have been previously extended;

(iii) the product must have been subject to a regulatory review period before its commercial marketing or use; and

(iv) the permission for commercial marketing or use must constitute the first permitted marketing or use of the product under the provision of law under which the regulatory review period occurred.

With respect to (j) above, the USPTO construes the claims of a patent to determine whether at least one claim encompasses the approved product. The USPTO interprets a claim as encompassing the approved product if it encompasses either the medical device as a whole, or any component part of the medical device. Based on a strict statutory interpretation of section 156, one may conclude that a patent claiming a component part of a medical device would not be eligible for extension because the patent does not claim the product, where "product" means the complete medical device. The USPTO does not believe that this was the intent of Hatch-Waxman and liberally construes the statutory provision requiring that a patent claim a product.

Assuming that there are multiple patents for which each of the requirements of Section 156 is met, a patentee may file patent term extension applications for multiple patents based on a single regulatory review period, provided that in no event shall more than one patent be extended for the same regulatory review period for any product, as provided for in 35 U.S.C. § 156(c)(4). Therefore, when the USPTO receives multiple patent term extension applications for a single regulatory review period from a single applicant, the applicant for patent term extension is required to elect a single patent for extension pursuant to 37 C.F.R. § 1.785.

Regarding *Cardiac Pacemakers v. St. Jude*, 381 F.3d 1371 (Fed. Cir. 2004), the USPTO understands the Federal Circuit to have held that extensions under 35 U.S.C. § 156 were not required to be based on the first approved medical device covered by the patent, but on the first permitted commercial marketing or use of the product, which is one of the statutory requirements highlighted above. The Federal Circuit confirmed that only one extension per patent is available, another statutory requirement highlighted above. Your conclusion that a component patent holder could apply for extension, even if the component was in a medical device that was previously approved, is correct, provided that the requirement of 35 U.S.C. § 156(a)(5)(A) is met. That is, the first approved product cannot be the same device as the second approved product. The first approved product would bar extension of the second approved product, because the second approved product would not "constitute the first permitted commercial marketing or use of the product under the provision of law under which the regulatory review period occurred."

The determination of whether a product complies with § 156(a)(5)(A) is within the purview of the particular department at FDA charged with reviewing and ultimately determining permission for commercial marketing or use of the product subject to a regulatory review period. For medical devices, the Center for Devices and Radiological Health would be the reviewing entity and would be consulted for determining whether an approved product, for which patent term extension is sought, constitutes the first permitted commercial marketing or use as required by § 156(a)(5)(A). Therefore, because FDA possesses the information necessary to determine whether a reviewed product is the same as a previously reviewed product, the USPTO is not the best source to answer the question presented at the fourth paragraph of your letter; that is, "Would the device subject to the second FDA review be considered a new device for which the patent

of any component could be extended or would it be considered a second review of an already approved device?" We have, however, forwarded a copy of your letter to Mr. Stephen Mason, the Associate Commissioner for Legislation at FDA, requesting that an appropriate answer to this question be provided to you. For your information, a copy of our letter to Mr. Mason is enclosed.

Specifically, the determination of whether a patent claiming an improvement of a previously approved medical device is eligible for patent term extension depends upon whether the second approved medical device is a product different enough from a previously approved medical device, such that the permission for commercial marketing or use of the second medical device "constitutes the first permitted commercial marketing or use of the product." Should an application for patent term extension be submitted to the USPTO with the facts outlined in the fourth paragraph of your letter, the USPTO would determine initial eligibility, but would defer the question to FDA of whether "the permission for commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product." For example, the USPTO is currently assessing the eligibility of a patent for patent term extension based on the regulatory review of a medical device. The USPTO and FDA initially concluded that the permission for the commercial marketing or use of the medical device was not the first permitted commercial marketing or use in light of the patentee's earlier approved device.[1] The patentee requested reconsideration alleging differences between the medical device serving as the basis for extension and the earlier approved device. The USPTO asked FDA for their input as to whether the differences set forth by the patentee suffice to render the medical device serving as the basis for extension different from the earlier approved device, such that the second approval constitutes the "first permitted commercial marketing or use."

At the fourth paragraph on page one of your letter, you also ask whether a second review of a previously approved device would negate the possibility of extending a patent on any of its components. Presuming that the device subject to the second FDA review is not considered to be different from the previously approved device, each patent claiming a component part of a medical device would be seeking extension based on a permitted commercial marketing or use that is not the first permitted commercial marketing or use. On the other hand, if a patented component was not a part of the device during the first review, eligibility for patent term extension would be premised on the patented component rendering the device subject to the second FDA review different from the previously approved device. In such case, the second FDA review and permission for commercial marketing or use would appear to constitute the first permitted commercial marketing or use.

At page two, you state "[w]hat if the patented component, when first introduced to market, was not subject to FDA review and only later was incorporated into a device that

[1] See the Image File Wrapper for U.S. Patent No. 5,299,569, available on Public PAIR at http://portal.uspto.gov/external/portal/pair.

required FDA review." Based on this statement, you question whether the review would permit extension of the patent claiming the component.

The critical inquiry regarding eligibility of a patent for patent term extension is whether any subsequent permission for commercial marketing or use meets the requirement of § 156(a)(5)(A). That is, whether the permission for the commercial marketing or use of the product after a regulatory review period constitutes the first permitted commercial marketing or use of the product. The USPTO is of the opinion that if a patent claims a component of a medical device which was subject to a regulatory review period within the meaning of §156(g), then the patent would be eligible for extension regardless of a previous incorporation of the patented component in a non-regulated product, presuming compliance with the statutory requirements of § 156.

At the second paragraph on page two, you inquire whether an extension based on a patent claiming a component unfairly extends the length of a patent; in particular, when a patented component was previously part of a non-regulated product. Your inquiry relates to section 156(b), which is commonly referred to as the "rights derived" section and relates to enforcement. Although the USPTO is not involved in enforcement actions, the USPTO understands that the rights derived from a patent term extension must be consistent with the eligibility requirements. Thus, the product subject to a regulatory review period is the complete product, thereby giving rise to eligibility for term extension of a patent claiming a component of the product. For example, in the case of a medical device, it is the whole device, not just the component claimed in the patent, and the scope of extension is limited to the complete approved product. This understanding is reflected in the practice articulated in the *Manual of Patent Examining Procedure*, MPEP 2750, which is available on the USPTO's web site, www.uspto.gov.

In the penultimate paragraph of your letter, you state that "§ 156 provides that the scope of an extended patent is 'limited to any use approved for the product.'" You ask how this limitation would be applied to a medical device component. Permission for commercial marketing or use of a regulated product by FDA is limited to the use for which clinical testing was performed. The marketing applicant before the FDA, after the approval of the product for a specific use, can conduct additional clinical investigations on the same device and, presumably, those other uses of the same product would be covered by the product patent during the extended period. For example, a medical device, originally approved by FDA for use in clearing cardiac arterial blockages in patients, could be later approved for use in clearing femoral arterial blockages. During the extended period, the patentee could enforce the patent for the medical device for each use.

Because the rights derived during the extended period are limited to the scope of the approved product and the approved uses (as well as any subsequent approved uses of the approved product), the extension appears to be limited to compensating for time lost due to regulatory delay. The USPTO understands that the policy behind the Hatch-Waxman Act was to compensate patentees for delay in bringing products to the market which, prior to commercial marketing or use, are required to undergo a regulatory review period.

Consistent with the intentions of Hatch-Waxman, the product subject to regulatory review, claimed in a patent, is eligible for extension if the patent meets the statutory requirements of § 156. Therefore, any rights during the extended period are limited to the product subject to regulatory review. Therefore, whether a "substantially equivalent" product, reviewed and cleared by FDA under § 510(k) of the Federal Food Drug and Cosmetic Act, would be encompassed by the patent during the extended term is not an issue which the USPTO had had to address. Should FDA clear such a medical device, there would appear to be issues with patent rights for clearance under 510(k) if the 510(k) application is not submitted by the patentee as the original marketing applicant.

Please let me know if you have any questions or need additional information.

Sincerely,

Jefferson D. Taylor
Director
Office of Governmental Affairs

Enclosure